

EXHIBIT A

FILED
TRUST

APR 18 2008

CLERK OF SUPERIOR COURT
HUDSON COUNTY

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**IN THE SUPERIOR COURT OF NEW JERSEY
LAW DIVISION, HUDSON COUNTY**

JERRY CASTLEBERRY, as the Representative)
Of the Estate of Donnia Castleberry,)

Plaintiff,)

v.)

NOVARTIS PHARMACEUTICALS)
CORPORATION;)
NOVARTIS CORPORATION;)
NOVARTIS PHARMA STEIN AG;)
NOVARTIS AG; and)
DOES 1 through 350, inclusive)

Defendants.)

**SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: HUDSON COUNTY**

Docket No. *L 1943-08*

CIVIL ACTION

**COMPLAINT and
JURY TRIAL DEMAND**

Plaintiff, Jerry Castleberry, as Representative of the Estate of Donnia Castleberry, deceased, by and through his attorneys, SimmonsCooper LLC and Lopez McHugh, LLP, hereby sue the defendants, Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis

Pharma Stein AG, and Novartis AG, and for his causes of action, alleges and states as follows:

THE PARTIES

1. Plaintiff Decedent, Donnia Castleberry, was a United States citizen and resided at 131 Millionaire Lane, Benton, Kentucky. Donnia Castleberry was born on March 30, 1941. Donnia Castleberry died July 10, 2007.

2. Plaintiff, Jerry Castleberry, is a United States citizen, residing at 84 Blue Bird Lane. Plaintiff Jerry Castleberry is the son of Plaintiff Decedent, and was appointed Fiduciary of the Estate of Donnia Castleberry by the District Court of the State of Kentucky on April 15, 2008. Jerry Castleberry, on behalf of the estate of Donnia Castleberry, seeks compensatory and punitive damages for her injuries, proximately caused by the negligent, wanton and willful conduct of the defendants in designing, formulating, preparing, manufacturing, labeling, marketing, distributing, and promoting the dangerous prescription drug Zelnorm and in failing to provide adequate warnings of its harmful effects.

3. Defendant, Novartis Pharmaceuticals Corporation, is a corporation organized and existing under the laws of Delaware, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936. At all times relevant, Novartis Pharmaceutical Corporation was wholly owned by Novartis Corporation.

4. At all times relevant hereto, Novartis Pharmaceuticals Corporation was engaged in the business of testing, researching, designing, formulating, preparing, developing, manufacturing, distributing, labeling, promoting and marketing, either directly or indirectly through third parties or related entities, the prescription drug Zelnorm (tegaserod maleate).

5. Defendant, Novartis Corporation, is a corporation organized and existing under the laws of New York, with its principal place of business at One South Ridgedale Avenue, East

Hanover, New Jersey, 07936. At all times relevant, the ultimate parent of Novartis Corporation was Novartis AG.

6. At all times relevant hereto, Novartis Corporation was engaged in the business of testing, researching, designing, formulating, preparing, developing, manufacturing, distributing, labeling, promoting and marketing, either directly or indirectly through third parties or related entities, the prescription drug Zelnorm.

7. Defendant, Novartis Pharma Stein AG, is a Swiss company with its principal place of business at Postfach CH-4332 Stein, Switzerland. At all times relevant, the ultimate parent of Novartis Pharma Stein AG was Novartis AG.

8. At all times relevant hereto, Novartis Pharma Stein AG was engaged in the business of testing, researching, designing, formulating, preparing, developing, manufacturing, distributing, labeling, promoting and marketing, either directly or indirectly through third parties or related entities, the prescription drug Zelnorm.

9. Defendant, Novartis AG, is a Swiss company with its principal place of business at Basel, Switzerland.

10. At all times relevant hereto, Novartis AG was engaged in the business of testing, researching, designing, formulating, preparing, developing, manufacturing, distributing, labeling, promoting and marketing, either directly or indirectly through third parties or related entities, the prescription drug Zelnorm.

1. Plaintiff is informed and believes, and thereupon allege, that DOES 1 through 50, inclusive, whose specific identities and liability for Plaintiff's injuries are currently unknown to the Plaintiff, are the individuals, business entities, and corporations within the chain of

commerce, that distributed Zelnorm to Plaintiff and other members of the American consuming public. Plaintiff will seek leave of court to amend this Complaint to identify DOES 1 through 50, referred to herein as "Distributor Defendants," upon determining the identities, and factual basis for the potential liability, of said Defendants.

2. Plaintiff is informed and believes, and thereupon allege, that DOES 51 through 100, inclusive, whose specific identities and liability for Plaintiff's injuries are currently unknown to the Plaintiff, are the individuals, business entities, and corporations within the chain of commerce, that manufactured Zelnorm for marketing, sale, and distribution to Plaintiff and other members of the American consuming public. Plaintiff will seek leave of court to amend this Complaint to identify DOES 51 through 100, referred to herein as "Manufacturer Defendants," upon determining the identities, and factual basis for the potential liability, of said Defendants.

3. Plaintiff is informed and believes, and thereupon alleges, that DOES 101 through 150, inclusive, whose specific identities and liability for Plaintiff's injuries are currently unknown to Plaintiff, are the individuals, business entities, and corporations within the chain of commerce, that marketed and sold Zelnorm by way of wholesale distribution and sale for ultimate retail sale and distribution to Plaintiff and other members of the American consuming public. Plaintiff will seek leave of court to amend this Complaint to identify DOES 101 through 150, referred to herein as "Wholesaler Defendants," upon determining the identities, and factual basis for the potential liability, of said Defendants.

4. Plaintiff is informed and believes, and thereupon alleges, that DOES 151

through 200, inclusive, whose specific identities and liability for Plaintiff's injuries are currently unknown to Plaintiff, are the individuals, business entities, and corporations within the chain of commerce, that marketed and sold Zelnorm by way of retail marketing and sale to Plaintiff and other members of the American consuming public. Plaintiff will seek leave of court to amend this Complaint to identify DOES 151 through 200, referred to herein as "Retailer Defendants," upon determining the identities, and factual basis for the potential liability, of said Defendants.

5. Plaintiff is informed and believes, and thereupon alleges, that DOES 201 through 250, inclusive, whose specific identities and liability for Plaintiff's injuries are currently unknown to the Plaintiff, are the individuals, business entities, and corporations within the chain of commerce, that marketed Zelnorm by way of advertising and marketing Zelnorm for sale to Plaintiff and other members of the consuming public. Plaintiff will seek leave of court to amend this Complaint to identify DOES 201 through 250, referred to herein as "Marketer Defendants," upon determining the identities, and factual basis for the potential liability, of said Defendants.

6. Plaintiff is informed and believes, and thereupon alleges, that DOES 251 through 300, inclusive, whose specific identities and liability for Plaintiff's injuries are currently unknown to the Plaintiff, are the individuals, business entities, and corporations within the chain of commerce, that compounded and formulated the pharmaceutical Zelnorm, which product was ultimately manufactured, packaged, labeled, advertised, marketed, distributed, and sold to plaintiff and other members of the consuming public. Plaintiff will seek leave of court to amend this Complaint to identify DOES 251 through 300, referred to herein as the "Formulator Defendants," upon determining the identities, and factual basis for the potential liability, of said Defendants.

11. Plaintiff is informed and believes, and thereupon alleges, that DOES 301 through 350, whose specific identities and liability for Plaintiff's injuries are currently unknown to the Plaintiff, are the individuals, business entities, and corporations within the chain of commerce, that in some manner were, at all times relevant to this action, engaged, separately or in combination, in the design, manufacture, testing, process of seeking FDA approval, for the manufacture and sale of Zelnorm, conducted and engaged in clinical studies regarding the safety and efficiency of Zelnorm, the packaging, labeling, advertising, marketing, distribution, prescribing, and/or sale of Zelnorm to plaintiff and other members of the consuming public. Plaintiff will seek leave of court to amend this Complaint to identify said DOE Defendants, upon determining the identities, and factual basis for the potential liability, of said Defendants.

CAUSES OF ACTION

COUNT I

New Jersey Products Liability Act – Defective Design (N.J.S.A. 2A:58C-2 *et seq.*)

12. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herewith.

13. At all material times, Defendants engaged in the business of testing, researching, designing, formulating, preparing, developing, manufacturing, distributing, labeling, promoting and marketing Zelnorm, and with willful and wanton disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the Zelnorm was not reasonably fit, suitable, or safe for its intended purpose.

14. With willful and wanton disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants placed Zelnorm in the stream of commerce in a

defective design or formulation in that, when it left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

15. The defective condition of Zelnorm renders it unreasonably dangerous, and Zelnorm was in this defective condition at the time it left the hands of the Defendants. Zelnorm was expected to and did reach consumers, including Donnia Castleberry, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise releases into the stream of commerce.

16. Donnia Castleberry was unaware of the significant hazards and defects of Zelnorm. Zelnorm was unreasonably dangerous in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Donnia Castleberry was taking Zelnorm, the medication was being utilized in a manner that was intended by Defendants. At the time Donnia Castleberry received and consumed Zelnorm, it was represented to be safe and free from latent defects.

17. Defendants are strictly liable to Donnia Castleberry for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects.

18. Defendants knew or should have known of the danger associated with the use of Zelnorm, as well as the defective nature of Zelnorm, but continued to design, manufacture, sell, distribute, market, promote and/or supply Zelnorm so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Zelnorm.

19. As a direct and proximate cause of the design defect and Defendants' misconduct

as set forth herein, Donnia Castleberry has suffered serious and permanent physical and emotional injuries, has expended large sums of money for medical care and treatment, has suffered economic loss, and has otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

New Jersey Products Liability Act - Failure To Warn (N.J.S.A. 2A:58C-2 *et seq.*)

20. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herewith.

21. At all material times, Defendants designed, formulated, prepared, researched, tested, manufactured, inspected, packaged, labeled, marketed, distributed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical Zelnorm, and in the course of same, directly advertised or marketed the product to FDA, consumers such as Donnia Castleberry, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Zelnorm.

22. With willful and wanton disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants placed Zelnorm into the stream of commerce unaccompanied by appropriate warnings regarding all possible adverse effects and complications associated with the use of Zelnorm, and the comparative severity, duration and the extent of the risk of injury with such use.

23. With wanton and willful disregard for the safety of the public and for the safety of

Plaintiff Donnia Castleberry, Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of Zelnorm so that no medical care provider would have prescribed, or no consumer, such as Donnia Castleberry, would have used Zelnorm had those facts been made known to such providers and consumers.

24. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants provided warnings and information to the medical community, the consuming public, and Plaintiff Donnia Castleberry that did not accurately reflect the symptoms, scope or severity of the potential adverse effects.

25. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants failed to perform or otherwise facilitate adequate testing in that such testing would have shown that Zelnorm posed serious and potentially life-threatening adverse effects and complications, with respect to which full and proper warnings accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA and the public, including Plaintiff Donnia Castleberry.

26. Zelnorm, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known of the risk of serious and potentially life-threatening adverse effects and complications, such as heart attack, stroke, and death from the use of Zelnorm, Defendants failed to provide adequate warnings to medical care providers, the FDA, and the consuming public, including Donnia Castleberry, and continued to promote Zelnorm aggressively.

27. As direct and proximate result of the conduct of Defendants as aforesaid, Donnia

Castleberry suffered serious and permanent physical and emotional injuries, has expended large sums of money for medical care and treatment, has suffered economic loss, and has otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III

Breach of Implied Warranty Of Merchantability (N.J.S.A. 12A:2-314)

28. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herewith.

29. Defendant pharmaceutical companies designed, formulated, prepared, researched, tested, manufactured, packaged, labeled, marketed, distributed, promoted and sold the Zelnorm that Donnia Castleberry ingested.

30. The Zelnorm that Donnia Castleberry ingested was expected to, and did reach the Plaintiff without a substantial change in condition.

31. When Defendants placed the drug into the stream of commerce, they knew of the use for which the drug was intended and expressly and impliedly warranted to Donnia Castleberry that Zelnorm was merchantable and fit for the ordinary purpose intended.

32. Donnia Castleberry reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and upon the express and/or implied warranty that the drug was of merchantable quality and fit for use as represented by Defendants.

33. This warranty was breached because Zelnorm was not safe and effective as a medication for treatment of functional bowel disorders, as Defendants had represented with

wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry. The drug was not of merchantable quality; rather it was unsafe and unfit for its intended use, and unreasonably dangerous.

34. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants, their agents and employees also failed to provide adequate warnings, packaging, and labeling with Zelnorm, rendering it unreasonably dangerous and unfit for the intended and/or reasonably foreseeable purposes of use, in breach of this warranty.

35. As direct and proximate result of the conduct of Defendants as aforesaid, Donnia Castleberry suffered serious and permanent physical and emotional injuries, has expended large sums of money for medical care and treatment, has suffered economic loss, and has otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV

Breach of Express Warranty

36. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herewith.

37. Defendants placed Zelnorm into the stream of commerce for sale and recommended its use to physicians, the FDA, and consumers without adequately warning of the risks associated with the use of Zelnorm.

38. Defendants had a duty to exercise reasonable care in the research, development,

design, testing, manufacture, inspection, labeling, distribution, marketing, promotion, sale and release of Zelnorm, including a duty to:

- (a) Ensure that the product did not cause the user unreasonably dangerous side effects;
- (b) Warn of dangerous and potentially fatal side effects; and
- (c) Disclose adverse material facts when making representation to physicians, the FDA and the public at large, including Donnia Castleberry.

39. When Donnia Castleberry's physicians(s) prescribed Zelnorm and Donnia Castleberry made the decision to use Zelnorm, both Donnia Castleberry and her physician(s) reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers and side effects of Zelnorm.

40. Donnia Castleberry's physician(s), the FDA and/or Donnia Castleberry had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning Zelnorm when Donnia Castleberry's physician prescribed and/or otherwise provided Zelnorm and Donnia Castleberry purchased and used Zelnorm as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by the Defendants. Donnia Castleberry justifiably and detrimentally relied on the warranties and representations of Defendants in the purchase and use of Zelnorm.

41. Defendants were under a duty to disclose the defective and unsafe nature of Zelnorm to physicians, the FDA, consumers and users, such as Donnia Castleberry. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians, the FDA and users, such as Donnia Castleberry, could not have reasonably discovered such

defects.

42. By the conduct alleged, Defendants, their agents and employees expressly warranted to Donnia Castleberry and Donnia Castleberry's physician(s) that the products were merchantable and fit for the purpose intended, in violation of N.J.S.A. 12A:2-313 *et seq.*

43. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants breached their warranty in that Zelnorm was not safe and effective for its intended, reasonably foreseeable use as a medication for functional bowel disorders, and Donnia Castleberry was injured.

44. The Zelnorm that Donnia Castleberry ingested reached her without a substantial change in condition from the condition in which Defendants manufactured, sold, distributed, marketed, and/or promoted it.

45. As a direct result of Defendants' conduct as aforesaid, Donnia Castleberry has suffered serious and permanent physical and emotional injuries, has expended large sums of money for medical care and treatment, has suffered economic loss, and has otherwise been, physically, emotionally and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V

Negligence

46. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herewith.

47. At all material times, Defendants had a duty to exercise reasonable care, and to

comply with the existing standard of care, in testing, researching, designing, formulating, preparing, marketing, developing, manufacturing, distributing, labeling, promoting and selling of Zelnorm which they introduced into the stream of commerce, including a duty and obligation to insure that Zelnorm did not cause users to suffer from unreasonable, dangerous or untoward adverse side effects.

48. At all material times, Defendants had a duty to consumers to exercise reasonable care, and to comply with the existing standard of care, in warning of the risks, dangers, and adverse side effects of Zelnorm.

49. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants breached their duty of care, and failed to exercise ordinary care in the testing, researching, designing, formulating, preparing, inspecting, warning, marketing, developing, manufacturing, distributing, labeling, promoting and selling of Zelnorm which it introduced into the stream of commerce, because Defendants knew or should have known that Zelnorm created the risk of unreasonable, dangerous or untoward adverse effects.

50. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants breached the standard of care, and failed to use reasonable care, in the manner in which they prepared, designed, researched, tested, developed, manufactured, inspected, labeled, marketed, promoted, and sold Zelnorm.

51. Despite the fact that Defendants knew, or reasonably should have known, that Zelnorm caused unreasonable and dangerous side effects, including, but not limited to heart attacks and strokes which many users would be unable to remedy by any means, Defendants, in conscious, wanton and willful disregard of the foreseeable harm caused by Zelnorm, continued to promote and market Zelnorm to consumers, including Donnia Castleberry, when safer,

alternative pharmaceutical agents for the treatment of symptoms related to IBS.

52. Defendants knew, or reasonably should have known, that consumers such as Donnia Castleberry would foreseeably suffer injury as a result of Defendants' failure to exercise due care, and their failure to comply with the standard of care, as set forth above.

53. As a direct result of Defendants' conduct as aforesaid, Donnia Castleberry has suffered serious and permanent physical and emotional injuries, has expended large sums of money for medical care and treatment, has suffered economic loss, and has otherwise been, physically, emotionally and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI

Fraud and Misrepresentation

54. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herewith.

55. Defendants, having undertaken the testing, researching, designing, formulating, preparing, developing, manufacturing, distributing, labeling, promoting and marketing of Zelnorm, owed prescribing physicians, the FDA, and public, including Donnia Castleberry, a duty to provide accurate and complete information regarding this product.

56. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants' advertising program, by affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that Zelnorm was safe and did not have unacceptable adverse effects when used as directed.

57. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants misrepresented to Donnia Castleberry and the public their knowledge about the likelihood that Zelnorm would cause injuries such as Plaintiff's. Defendants concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of Zelnorm. Defendants falsely and deceptively kept relevant information from Zelnorm users and minimized concerns regarding the safety of Zelnorm to induce Donnia Castleberry and the public to purchase and use Zelnorm.

58. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from Donnia Castleberry and her prescribing physician in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and use of Zelnorm.

59. Defendants' statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including Donnia Castleberry, would rely on the statements and/or omissions.

60. Defendants knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Zelnorm but in conscious, wanton and willful disregard of the foreseeable harm caused by Zelnorm, remained silent because Defendants' appetites for significant future profits far outweighed their concern for the health and safety of consumers.

61. Defendants' practice of promoting and marketing Zelnorm created and reinforced a false impression as to the safety of Zelnorm, thereby placing consumers at risk of serious and

potentially lethal effects.

62. At the time of Defendants' fraudulent misrepresentations, Donnia Castleberry was unaware of the falsity of the statements being made and believed them to be true.

63. Donnia Castleberry and her prescribing physician justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information.

64. Defendants had a post-sale duty to warn Donnia Castleberry and her prescribing physician about the potential risks and complications associated with Zelnorm in a timely manner.

65. Defendants' representations, misrepresentations, acts and omissions deprived Donnia Castleberry and other foreseeable Zelnorm users of free choice whether to expose themselves to its dangers.

66. As a direct result of Defendants' conduct as aforesaid, Donnia Castleberry has suffered serious and permanent physical and emotional injuries, has expended large sums of money for medical care and treatment, has suffered economic loss, and has otherwise been, physically, emotionally and economically injured.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII

Violation Of New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1 *et seq.*)

67. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herewith.

68. Prescription drugs such as Zelnorm are “merchandise,” as that term is defined by N.J.S.A. 56:8-1 *et seq.*

69. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and/or otherwise released Zelnorm into the stream of commerce.

70. Defendants knew or should have known that the use of Zelnorm causes serious and life threatening injuries but failed to warn the public, including Donnia Castleberry, of same.

71. With wanton and willful disregard for the safety of the public and for the safety of Plaintiff Donnia Castleberry, Defendants made untrue, deceptive, fraudulent misrepresentations of material facts and knowingly concealed, suppressed and/or omitted material facts in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and use of Zelnorm. Moreover, Defendants downplayed and/or understated the serious nature of the risks associated with Zelnorm in order to increase the sales of Zelnorm.

72. Defendants’ statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including Donnia Castleberry, would rely on the Defendants’ statements and/or omissions.

73. Defendants knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Zelnorm but remained silent because Defendants’ appetite for significant future profits far outweighed their concern for the health and safety of the Donnia Castleberry.

74. Defendants concealed, omitted, or minimized the side effects of Zelnorm or provided misinformation about adverse reactions, risks and potential harms from Zelnorm and

succeeded in persuading consumers to purchase and ingest Zelnorm despite the lack of safety and the risk of adverse medical reactions.

75. Defendants' practice of promoting and marketing Zelnorm created and reinforced a false impression as to the safety of Zelnorm, thereby placing consumers at risk of serious and potentially lethal effects.

76. Donnia Castleberry's physician prescribed and/or otherwise provided Donnia Castleberry with Zelnorm, and Donnia Castleberry consumed Zelnorm and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices alleged herein.

77. Defendants' above-described promotion and release of Zelnorm into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression, or omission in connection with the sale or advertisement of such merchandise in violation of N.J.S.A. 56:8-1 *et seq.*

78. Zelnorm lacked appropriate warnings, and the packaging and labels used by Defendants were misleading, inaccurate, incomplete, and/or untimely.

79. Defendants violated their post-manufacture duty to warn which arose when Defendants knew, or with reasonable care should have known, that Zelnorm was injurious and sometimes fatal.

80. At the time when consumers purchased and ingested Zelnorm, Defendants intended that others would rely upon the concealment, suppression or omission of the risks of ingesting Zelnorm.

81. Defendants' actions in connection with manufacturing, distributing, and marketing of Zelnorm as set forth herein evidence a lack good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commerce practices, in violation of the New Jersey Consumer Fraud Act., N.J.S.A., 56:8-1 *et seq.*

82. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

83. As a proximate result of the acts of consumer fraud set forth above, Donnia Castleberry purchased an unsafe product and incurred monetary expense and the risk to her and members of her household that they would consume Zelnorm and thereby suffer an increased risk of harm as previously set forth herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII

Punitive Damages Under the New Jersey Products Liability Act (N.J.S.A. 2A:58C-1)

84. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herewith.

85. Plaintiff is entitled to punitive damages because the Defendants' failure to warn was reckless and without regard for the public's safety and welfare. The Defendants misled both the medical community and the public at large, including Donnia Castleberry herein, by making false representations about the safety of Zelnorm. Defendants downplayed, and understated and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Zelnorm despite available information demonstrating that Zelnorm was likely to

cause serious and even fatal side effects to users.

86. Defendants were or should have been in possession of evidence demonstrating that Zelnorm caused serious side effects. Nevertheless, Defendants continued to market Zelnorm by providing false and misleading information with regard to safety and efficacy.

87. Defendants failed to provide warnings that would have dissuaded physicians from prescribing Zelnorm and consumers from purchasing and consuming Zelnorm, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Zelnorm.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

RELIEF REQUESTED

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

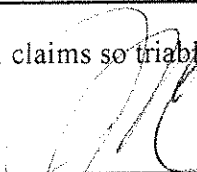
- A. Awarding Plaintiff compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- B. Awarding Plaintiff treble damages against Defendants so as to fairly and completely compensate Plaintiff for all damages, and to deter similar wrongful conduct in the future;
- C. Awarding Plaintiff punitive damages against Defendants in an amount sufficient to punish Defendants for their wrongful conduct and to deter similar wrongful conduct in the future;
- D. Awarding Plaintiff costs and disbursements, costs of investigations, attorneys' fees and all such other relief available under New Jersey law;

- E. Ordering that the costs of this action be taxed to Defendants; and
- F. Awarding such other and further relief as the Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff demands a trial by jury as to all claims so triable in this action.

Dated:



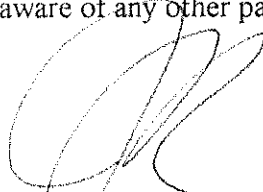
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CERTIFICATION PURSUANT TO RULE 4:5-1

Plaintiff upon information and belief is not aware of any pending or contemplated action.

Further, upon information and belief, she is not aware of any other party who should be joined in this action.

Dated:

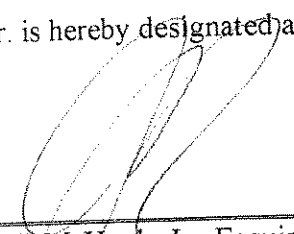


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DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, James J. McHugh, Jr. is hereby designated as trial counsel in this matter.

Dated:

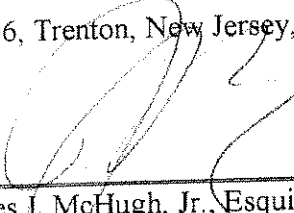


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CERTIFICATION OF NOTICE

Pursuant to N.J.S.A. 56:8-20, Plaintiff is mailing a copy of this Complaint and Jury Demand to the Office of Attorney General, Cn-006, Trenton, New Jersey, within (10) days of the filing of this Complaint and Jury Demand.

Dated:



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